

### REMARKS

No amendments are made in this response. Applicants respectfully request favorable reconsideration of the application, in view of the following remarks.

#### Status of the Claims

Claims 1-38 and 40-60 are pending. Claim 39 stands canceled.

#### Claim Objections

Claim 8 was objected to for being improperly identified by the status identifier as being “Currently amended” in the Applicants’ prior response. Correction to the claim has been made to identify the claim as “Original” in the listing of claims presented with this response.

#### The 35 U.S.C. 103(a) rejections

##### I. Therriault *et al.* (US 4,904,247) and Inaba *et al.* (4,552,751)

Claims 1-38 and 40-60 are rejected as allegedly unpatentable over the combination of Therriault *et al.* (US 4,904,247; herein “Therriault”) and Inaba *et al.* (4,552,751; herein “Inaba”). Applicants respectfully traverse the rejection.

For the record, Applicants object to the Office’s characterization of the pending claim 1 at page 4 of the Office Action. Pending claim 1 as currently amended reads:

1. (Previously presented) A composition comprising:
  - (a) a hydrogel comprising:
    - (i) a water-swellaable, water-insoluble polymer;
    - (ii) a blend of a hydrophilic polymer with a complementary oligomer capable of hydrogen or electrostatic bonding to the hydrophilic polymer; and
    - (iii) an active agent; and
  - (b) an outer backing member, where the backing member is comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel.

The Office’s characterization ignores certain features of the claim. For example, the Office’s characterization leaves out the features that the claimed composition comprises a hydrogel and that the backing member erodes in a moist environment at a slower rate than the hydrogel. Polymers in (i) and (ii) are such that their combination forms a hydrogel. The backing member provides an

outer backing to protect the hydrogel by having a slower rate of erosion in a moist environment than the hydrogel itself.

Therriault teaches hydrophilic laminate compositions. Therriault states in the Summary of the Invention that:

The herein described laminate structures comprise, *as essential layers*, (1) at least one-tacky non-pressure-sensitive layer, which is capable of forming a hydrogel upon equilibration with water and imparts *strength, and bacterial barrier properties to the structure*; and (2) at least one tacky pressure-sensitive adhesive layer *for attachment to skin*. (Emphasis added).

The compositions are taught particularly for use as wound dressings, as the non-tacky hydrogel layer acts as an outer bacterial barrier, with the inner tacky layer functioning as an attachment point to the skin. The compositions may contain drugs, medicaments, or biologically active agents, and such agents are preferably in the non-tacky outer hydrogel layer (column 3 lines 21-25). Therriault teaches that the release of the drug can be controlled by choosing appropriate polymer constituent in the non-tacky outer hydrogel layer (column 3, lines 33-35).

Inaba teaches a multilayer film for extended release of the prostaglandin hormone. The films comprise at least two drug release controlling layers sandwiching one or more drug storing and releasing layers (column 2 lines 51-55 and Figures). This unique sandwich design of the multilayer film allows for controlled release of the prostaglandins for use intravaginally where both surfaces of the film can be in contact with the mucosa (see column 1 lines 44-54 and Fig. 1).

The prostaglandins must flow through the drug release layers prior to entry into the mucosa. The drug release layer therefore serves to control the release of the prostaglandins by mediating its transfer from the drug storage layer to the mucosa. Inaba teaches that the films work by allowing body liquids to permeate into and dissolve the inner drug storage layer. The drugs are then leached out, with the rate of release controlled by the nature of the drug release layers through which the drug must pass (column 2 lines 61 to column 3 lines 23).

The Office asserts that:

It would have been obvious to one having ordinary skill in the art at the time of the invention to provide laminate wherein each layer comprises hydrophilic composition comprising water swellable insoluble water-insoluble polymer, water soluble polymer,

oligomer and active agent as taught by Therriault, and replace one layer of the laminate with a layer that have slower solubility and erosion comprising cellulose derivatives as taught by Inaba. (Office action at page 6)

The Federal Circuit has held that “a proposed modification [is] inappropriate for an obviousness inquiry when the modification render[s] the prior art reference inoperable for its intended purpose.” *In re Fritch*, 972 F.2d at 1265 n. 12 (Fed. Cir. 1992; see also MPEP 2143.01 V). Given the advantages of strength and bacterial barrier properties of the essential non-tacky hydrogel layer touted by Therriault, any modifications that compromises these properties would run counter to the essence of Therriault’s invention.

Thus if the Office is suggesting that the outer hydrogel layer of Therriault be replaced with the erodible layer of Inaba, such a change would render Therriault’s invention unsatisfactory as the resulting composition would compromise the sturdy bacterial barrier essential to Therriault. The teachings in Therriault of a stable dressing therefore do not support such a combination.

If the Office is suggesting that the inner layer of Therriault be replaced, the resulting composition would not be the composition of the present claims since the inner layer would now erode more slowly than the outer layer. The Office states at page 6 that “One would reasonably expected formulating laminate wherein ... a second layer comprises polymer having slower erosion to provide long lasting release pattern of the active agent.” Modifying Therriault in this manner would result in the slower eroding layer being closer to the skin since Inaba teaches that the rate of drug release can be impeded by the layer(s) that it must pass through. Again, such a modification to Therriault would not result in a composition of the present claims.

## II. Therriault *et al.* (US 4,904,247) and Taplosky *et al.* (5,904,247).

Claims 1-38 and 40-41 and 60 are rejected as allegedly unpatentable over the combination of Therriault and Taplosky *et al.* (5,904,247; herein “Taplosky”).

Taplosky teaches water soluble, pharmaceutical carriers such as bilayer films having a erodible backing layer. Taplosky teaches the advantageous of the invention over prior bioadhesive gels and pastes: “... present invention offers increased residence time because of its *filmy* consistency and components” (column 4 lines 7-9, emphasis added). Taplosky highlights in the

Summary of the Invention the advantages afforded by the invention of “having an effective residence time, with minimal discomfort and ease of use” (column 3 lines 27-28). Consequently in Taplosky’s film the outer protective layer dissolves *before* the inner agent containing adhesive layer (column 5 lines 32-36). Doing so maximizes the residence time of the agent and minimizes discomfort by minimizing the residence time of the outer layer.

The Office asserts that:

It would have been obvious to one having ordinary skill in the art at the time of the invention to provide laminate wherein each layer comprises hydrophilic composition comprising water swellable insoluble water-insoluble polymer, water soluble polymer, oligomer and active agent as taught by Theriault, and replace one layer of the laminate with a the erodible backing taught by Taplosky. (Office action at pages 16-17)

Neither the teachings in Taplosky nor those in Theriault support such a combination. First, substituting the strong bacterial barrier of Theriault with an erodible backing would destroy the intended function of Theriault’s invention.

Secondly, Taplosky teaches away from use of gels by specifically disparaging gels and pointing out the superiority of their films over gels (column 4 lines 4-31).

Third, the proposed combination would result in a composition having a backing that erodes before the inner adhesive layer. Such a composition is not what is claimed.

The Office states that “one of ordinary skill in the art a the time of the invention would have been able to adjust the polymers to obtain the desired dissolution time of the backing layer according to the intended use and site of application.” The Office further states “Result-effective variables, such as dissolution rate can be optimized.” Office action at page 19.

However the Office has not pointed to any teachings in Taplosky that would motivate one of skill in the art to optimize the films in Taplosky by replacing one of the film layers with a gel in view of Taplosky’s teachings of the disadvantages of gels. The Office has also not pointed out why dissolution time of the backing layer would be optimized to be *slower* than the adhesive layer (and not merely that the times can be different) when in fact Taplosky specifically teaches otherwise.

III. Therriault and Inaba or Therriault and Taplosky, each combination in view of Sagel *et al.* (US 5,891,453)

Claims 42-49 are rejected as allegedly unpatentable over the combination of Therriault and Inaba, or the combination of Therriault and Taplosky, each combination in view of Sagel *et al.* (US 5,891,453; herein "Sagel").

Sagel teaches dental strips where a teeth whitening agent preferably in a viscous state is applied to the side of the strip facing the teeth (column 3 lines 1-9) .

The Office asserts that one of skill in the art would replace the active agent in Therriault/Inaba/Taplosky with the tooth whitening agent of Sagel.

For the reasons stated above, the combination of Therriault/Inaba and Therriault/Taplosky are unsupported by the teachings in those references. Moreover Therriault, which is central to the rejections, teaches compositions having a strong bacterial barrier. Notwithstanding the fact that the compositions of Therriault are not the compositions of the present claims, one of skill in the art would not look to use Therriault's compositions as a carrier for a tooth whitening agent because there would be no need for a robust bacterial barrier in teeth whitening applications.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Favorable reconsideration and allowance of the pending claims is respectfully requested.

If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 590-0717.

Respectfully submitted,  
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